

REMARKS

The Examiner objected to Figure 1 because it fails to show tip 21. Tip 21 has been added to Figure 1. The red lined drawing sheet is attached. Applicant will defer submission of formal drawings until allowance of the application.

Claims 14 and 15 were objected to as being multiple dependent claims. Claims 14 and 15 have been amended to remove their dependence on claim 12. Accordingly, examination of claims 14 and 15 is respectfully requested.

Claim 6 has been amended for clarification to correct a misspelling.

The Examiner rejected claims 1 and 5-19 under 35 USC 112, second paragraph, as being indefinite. Referring to claim 1, the Examiner states that there is insufficient antecedent basis for "the outer tube", "the balloon membrane", "the tip", "the inner tube", and "the fiberoptic sensor".

Claim 1 is reproduced below:

1. A balloon catheter comprising a balloon membrane, a tip, a fiberoptic sensor connected to said tip, a fiberoptic fiber, an outer tube, and an inner tube disposed within an outer surface of said outer tube, said inner tube extending beyond a distal end of the outer tube, a distal end of the balloon membrane being connected to the tip and to a distal end of the inner tube, said fiberoptic fiber being connected on a distal end to the fiberoptic sensor and proximal to the fiberoptic sensor being at least partially connected along its length to the inner tube.

It is clear that Applicant introduces a balloon membrane, a tip, a fiberoptic sensor, a fiberoptic fiber, an outer tube and an inner tube in the first three lines of claim 1.

Given Applicant's proper introduction of these limitation, the rejection should be withdrawn. This is the same case in claim 6, Applicant properly introduces "a balloon portion" on the fourth line. This is also the case for claim 8 where Applicant properly introduces a pressure sensing surface on the fifth line of the claim. This is the case for all of the limitations cited by the Examiner. Clarification or withdrawal of the rejection is respectfully requested.

New method claims 20-30 have been added. The Commissioner is authorized to withdraw all necessary fees from deposit account 04-0170. No matter has been added. Regarding claims 20 and 21: see the last paragraph of page 1 and first paragraph of page 2 which disclose use of dicrotic notch for inflation/deflation timing of IAB. See pages 5-7 for disclosure of IAB catheter and sensor structure and configuration. Furthermore, note that the entire application discusses how to measure a pressure signal through a fiberoptic sensor in an intra-aortic balloon catheter. Claims 22-20 are new method claims that parallel their counterpart device claims, thus, no new matter has been added. Claim 22 parallels claim 8, claim 23 parallels claim 9, claim 24 parallels claim 10, claim 25 parallels claim 12, claim 26 parallels claim 13, claim 27 parallels claim 14, claim 28 parallels claim 15, claim 29 parallels claim 6 and claim 30 parallels claim 11.

The Examiner rejected claims 1, 6, 7, 16 and 17 under 35 USC 102(b) as being anticipated by US Patent No. 5,795,325, issued to Valley et al. (hereinafter referred to as "Valley"). Applicant respectfully traverses this rejection.

The Examiner refers to Figures 7A-7C and states that Valley discloses a fiberoptic sensor (330) and a fiberoptic

fiber (334 and 336). This is simply not the case. In column 17, lines 25-27, Valley discloses not a fiberoptic sensor but rather a pressure transducer (330) and not a fiberoptic fiber but rather wires (334 and 336). In column 17, lines 33-41, Valley elaborates and states that the pressure transducer is preferably a piezoelectric pressure transducer made from piezoelectric polymers such as polyvinylidene bifluoride or KYNAR or piezoelectric ceramics such as lead barium titanate. A fiberoptic sensor, which modifies the property of light as a function of pressure, is not the same thing as a pressure transducer. Furthermore, a fiberoptic fiber, which propagates light, is clearly not the same thing as a wire which propagates an electrical signal. Valley discloses nothing more than prior art, disclosed on page 2 of Applicant's application; namely, a balloon catheter with a tip mounted pressure transducer riddled with disadvantages, including its susceptibility to drift and electrical interference.


In column 33, lines 43-64, Valley discloses a fiberoptic illumination device including a fiberoptic bundle 155 either built into the wall of the catheter or removably inserted through an infusion lumen of catheter 154. The fiberoptic device is for transillumination of the aortic wall and for facilitating placement of the catheter. The fiberoptic bundle does not terminate in a fiberoptic sensor as required by claim 1. Nor is there any mention of using a fiberoptic sensor for measuring pressure. Note that connecting a fiberoptic sensor to the distal end of Valley's fiberoptic bundle would prevent light from escaping the distal end of the fiberoptic bundle, and thus, would prevent use of the bundle for the purposes taught by Valley. Accordingly, Valley in no way anticipates claims 1, 6, 7, 16 and 17.

The Examiner rejected claim 5 as being unpatentable over Valley in view of US Patent No. 5,370,640, issued to Kolff. The Examiner also rejected claims 8-13, 18 and 19 as being unpatentable over Valley in view of US Patent No. 5,795,325, issued to Weldon et al. Applicant respectfully traverses this rejection and reasserts the arguments made above. The disclosure of a catheter, including a pressure transducer and incorporating a fiberoptic bundle for illumination purposes, in no way renders obvious a catheter incorporating a fiberoptic sensor and fiber for monitoring pressure.

Should there remain unresolved issues that require adverse action, it is respectfully requested that the Examiner telephone Abraham Ronai, Applicants' Attorney at 201-307-5350 so that such issues may be resolved as expeditiously as possible.

Respectfully Submitted,

October 3, 2002
Date



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